REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance. If for some reason the Examiner does not believe the application is in condition for allowance, the Examiner is invited to contact the undersigned to discuss the above-identified application.

Claims 14-31 are pending in the application. Claims 14-28 have been amended to address the formal matters raised in the outstanding Official Action. Independent claim 14 has also been amended to recite a method for immunosuppression, prevention or treatment of infections in a human or animal patient. In this regard, the term "immunomodulation" is no longer recited in claim 14. Support for the changes to claims 14-28 may be found generally throughout the specification and in the original claims.

Claims 29-31 have been added. Support for the claims may be found generally throughout the application and in the original claims. Claim 29 is directed to a sialyzed carbohydrate and is supported in the specification at page 3, line 19 to page 4, line 24; page 5, lines 15-25; and page 7, lines 5-20. Claim 30 is directed to methods for treating infections by administering the sialyzed carbohydrates. Support for claim 30 may be found in the specification at page 10, lines 9-10. Claim 31 is directed to a food composition and I supported at page 11, lines 9-14.

In view of the above, Applicants most respectfully submit that no new matter has been added to the disclosure.

Claim 26 is objected to for reciting a first formula labeled I and II and a second formula labeled II. Claim 26 has been amended to correct the labeling of the formulas as suggested by the Examiner. Thus, applicants most respectfully ask that the objection be withdrawn.

Claims 14-23, 25 and 27-28 stand rejected under 35 U.S.C. 112, first paragraph, for allegedly not satisfying the enablement requirement.

Applicants respectfully submit that the present amendment obviates the rejection of claim 25.

As to the claims 14-23, Applicants respectfully submit that the Patent Office fails to satisfy its burden in showing the claimed invention does not satisfy the enablement requirement.

The Examiner is respectfully reminded of the well founded principle that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by the evidence or reasoning substantiating the doubt so expressed.

As a matter of law, the expressed teaching of the patent specification cannot be controverted by mere speculation and unsupported assertions on the part of the Patent Office. As stated by the Court of Customs and Patent Appeals in the case of *In re Dinh-Ngiyen and Stanhagen*, 181 USPQ 46 (CCPA 1974):

> Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported in evidence or reasoning substantiating the doubt so expressed. 181 USPQ at 47.

Such a standard must be applied with great care when the Examiner's conjecture is contrary to the teachings of the specification.

While the Official Action of January 24, 2007 cites to several documents (e.g., the Merck Index and WO0046379) in support of the enablement rejection, a careful review of those documents show that the documents only discuss the general state of the art. None of the publications contradict any of the statements made in the specification or could be considered as evidence that the claimed invention is not enabled. Indeed, at the bottom of page 4, the Official Action even acknowledges the probability that administration of the compounds has a reasonable expectation of success.

Rather, the Official Action makes the unsupported allegation that examples are

necessary without providing any reasons as to why one skilled in the art would not have understood how to practice and use the claimed invention absent any examples.

However, compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Contrary to the assertions of the Official action, the specification does teach how to practice the claimed invention. Indeed, the sialyzed carbohydrates are recited in the claims in terms of a chemical formula. In this regard, one skilled in the art would have readily understood the scope of the recited sialyzed carbohydrates. As to the claimed method, the present specification discusses in detail how to deliver the sialyzed carbohydrates to a patient beginning on page 8 of the specification. The present specification also contains six examples, which discuss how to prepare and deliver the sialyzed carbohydrates to a patient. For example, the first example discusses administering a composition in accordance with the present invention three times per day during meals.

In view of the above, Applicants respectfully submit that the Patent Office fails to satisfy its burden in showing that the claimed invention does not satisfy the enablement requirement.

As a result, the enablement rejection is improper as a matter of law and Applicants respectfully request that the rejection be withdrawn.

Claims 14-28 stand rejected under 35 U.S.C. 112, second paragraph, for allegedly being indefinite.

Claims 14 and 25 were rejected for reciting the term "several". Claims 14 and 25 have been amended so that this term is no longer recited.

Claim 14 was rejected because the meaning of V was allegedly unclear. However, independent claim 14 has been amended to clarify that the radical V in formula I has three different meanings i) OH, ii) a carbohydrate residue, or iii) a

connecting point to a carrier T. When a carrier T is present, the carrier T can be connected up to 50 carbohydrate units of general formula II, i.e., up to 50 single species of formula II each connected to the same carrier.

Claim 17 has been amended to recite an end group. Applicants thank the Examiner for the suggestion as how to overcome this aspect of the rejection.

Applicants respectfully submit that claim 20 is definite to one skilled in the art. While the recitation is broad, the recitation is definite to one skilled in the art. Indeed, Applicants submit that one skilled in the art would be able to determine an appropriate upper limit. Furthermore, Applicants note that the present specification does provide guidance on this matter in the form of Examples 1-6. Each of Examples 1-6 exemplify administering the compound of formula I in particular amounts and ranges. Examples 3-4 and 6 even discuss administering the recited compounds in terms of a range having an upper and lower limit. Thus, Applicants respectfully request that this aspect of the rejection be withdrawn.

Claim 25 has been amended so that the "other known active compounds and/or usual ingredients" is no longer recited.

In view of the above, Applicants respectfully request that the indefiniteness rejection be withdrawn.

Claim 24 stands rejected on the grounds of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 6 and 9-10 of U.S. Patent No. 6,576,251. This rejection is traversed.

The '251 patent relates to carbohydrate mixtures for foods and pharmaceuticals, wherein the carbohydrates have different chains and monosaccharide, disaccharide, and polysaccharide distributions. None of the claims of the '251 patent recite or suggest a compound of formula I or II. In this regard, it can be said that any of the claims in the present application would have been obvious in view of the '251 patent.

Furthermore, the Examiner's attention is respectfully directed to claims 1, 6 and 9 of the '251 patent. Contrary to the assertions of the Official Action, claim 1 recites that the composition contains "at least 1 wt.-% fucose". Dependent claims 6 and 9 rely on

claim 1 as a base claim. In other words, each of claims 1, 6, and 9 require the presence of fucose. In this regard, the claimed sialyzed carbohydrates stand in further contrast to the claims of the '251 patent.

Claim 10 has been canceled. Thus, the double patenting rejection pertaining to those clams has been rendered moot.

In view of the above, Applicants ask that the double patenting rejection be withdraw.

Claims 14-28 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Gilbert et al. This rejection is traversed.

GILBERT et al provide prokaryotic glycosyltransferases for the production of gangliosides and ganglioside mimics. GILBERT relates to the use of sialyltransferase in order to make sialated oligosaccharides (see abstract). The document explains that depending on the structure of the gangliosides, the gangliosides can have different effects

However, GILBERT et al do not disclose immunosuppressing, preventing, or treating an infection. Rather, It is stated that gangliosides can be used to mimic the outer shell of LPS. In Part E, GILBERT states that: "The oligosaccharide of the invention can be used as an immunogen for the production of monoclonal or polyclonal antibodies specifically reactive with the compounds of the invention".

Therefore, at best, the availability of the gangliosides could be used to study the immunogenic effects of bacteria having the LPS. No other specific uses are disclosed in this document.

Furthermore, the concrete teaching of the Gilbert reference starts on page 43, line 7. There it is stated that the oligosaccharides described in the Gilbert reference can be used for instance as diagnostic reagents.

If one compares this field with the pharmacological field of the present invention, then it becomes clear that the field of interest of the present invention is not only novel but also unobvious with respect to the compounds and compositions. A diagnostic

reagent is not a pharmaceutical composition for treating the above mentioned conditions.

It is also described in the Gilbert reference beginning on page 43, line 7 that the oligosaccharides as taught by the Gilbert reference can be used as an immunogen for the production of monoclonal or polyclonal antibodies.

The carbohydrates as used according to the present invention do not serve the purpose of producing antibodies. They are rather compounds used for medicinal purposes. A composition for producing an antibody is not a means for the immunomodulation, immunosuppression or prevention as well as treatment of infections of human beings and animals. According to the teaching of the Gilbert reference it is necessary to first prepare the antibodies by using the oligosaccharides there described. Said antibodies can then be used for medicinal purposes.

Contrary to the assertions of the Official Action, Applicants respectfully submit that GILBERT et al does not disclose an compound containing C as recited in claims 14-28. In the claims 14-28 C is HexNac, Hex, or absent, not glucocyl as shown in compound GT1a of Figure 4. As to claims 29-31, applicants respectfully submit that the GT1a compound fails to disclose or suggest V. Rather, GILBERT teaches that the molecule a fluorescent molecule is present.

Accordingly, GILBERT et al can not render obvious the claimed invention and applicants most respectfully request that the rejection be withdrawn.

In view of the present amendment and foregoing remarks, therefore, Applicants respectfully submit that the present application is in condition for allowance at the time of the next Official Action.

Respectfully submitted,
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